K022533

SEP 3 0 2002

510(k) Summary

FastPack® Testosterone Calibrator

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1.	**Submitter name, address, contact**	Qualigen, Incorporated 2042 Corte del Nogal Carlsbad, CA 92009	
		Telephone: Fax:	(760) 918-9165 (760) 918-9127
		Contact Person:	Dorothy Deinzer
		Date Prepared:	July 23, 2002
2.	**Device name**	Proprietary name:	FastPack® Testosterone Calibrator
		Common name:	Calibrator
		Classification Name:	Calibrator, Secondary
3.	**Predicate device**	Diagnostic Products Corporation's Coat-A-Count Total Testosterone RIA Kit (K844423), Calibrator component	
4.	**Intended use**	The FastPack® Total Testosterone Calibrator is intended to calibrate the FastPack® Analyzer system when used for the quantitative determination of testosterone in human serum.	

5. **Comparison to Predicate Device**

The following table compares the FastPack® Testosterone Calibrator with the calibrator component of the DPC Coat-A-Count® Total Testosterone:

Feature	FastPack® Testosterone Calibrator	DPC Coat-A-Count, Calibrator Component
Intended Use	For calibration of the FastPack® Analyzer system when used for the quantitative determination of testosterone in human serum.	The testosterone calibrator is intended to prepare the standard curve for the DPC Coat-A-Count assay kit for determination of total testosterone in human serum or heparinized plasma.
Analyte Matrix Form Volume	Total Testosterone Buffered Bovine Serum albumin Liquid 2.5 mL	Total Testosterone Human serum – based Liquid 0 level, 4.0 mL Other levels, 1.0 mL
Levels	1	6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Dorothy Deinzer
Director of Quality Assurance and Regulatory Affairs
Qualigen, Inc.
2042 Corte Del Nogal
Carlsbad, CA 92009

SEP 3 0 2002

Re: k022533
Trade/Device Name: FastPack® Testosterone Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: July 30, 2002
Received: July 31, 2002

Dear Ms. Deinzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 4

Indications for Use Statement

510(k) Number	K022533
Device Name	FastPack® Testosterone Calibrator
Indications for Use	The FastPack® Testosterone Calibrator is intended to calibrate the FastPack® Analyzer system when used for the quantitative determination of Testosterone in human serum.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022533

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)